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(54) **RUGGEDIZED ULTRASOUND HYDROGEL INSERT**

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(58) **Field of Classification Search**

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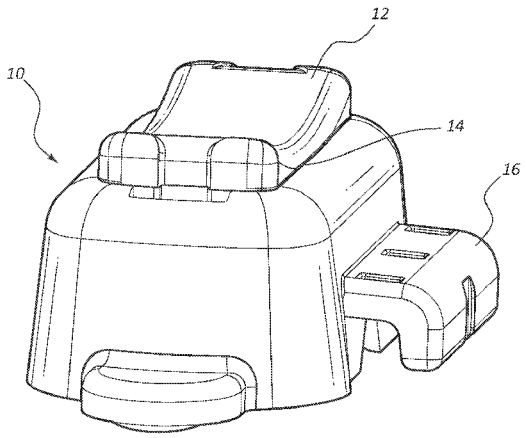
(57) **ABSTRACT**

A ruggedized hydrogel product that is formulated to withstand the effects of high-energy sterilization procedures, such as gamma beam and electron beam sterilization, without significant structural degradation is disclosed. This enables the hydrogel product to be suitable for use in medical applications where sterile components are required. In one embodiment a ruggedized hydrogel product is disclosed and comprises a gel component, water for hydrating the gel component, and at least one free radical absorber component that is capable of absorbing free radicals produced when the hydrogel product is sterilized via a high-energy sterilization procedure. The free radical absorber component in one embodiment includes potassium metabisulfite and ascorbic acid. The ruggedized hydrogel product can be included with an ultrasound probe to provide an acoustically transparent interface between the probe and the skin of a patient.

7 Claims, 9 Drawing Sheets



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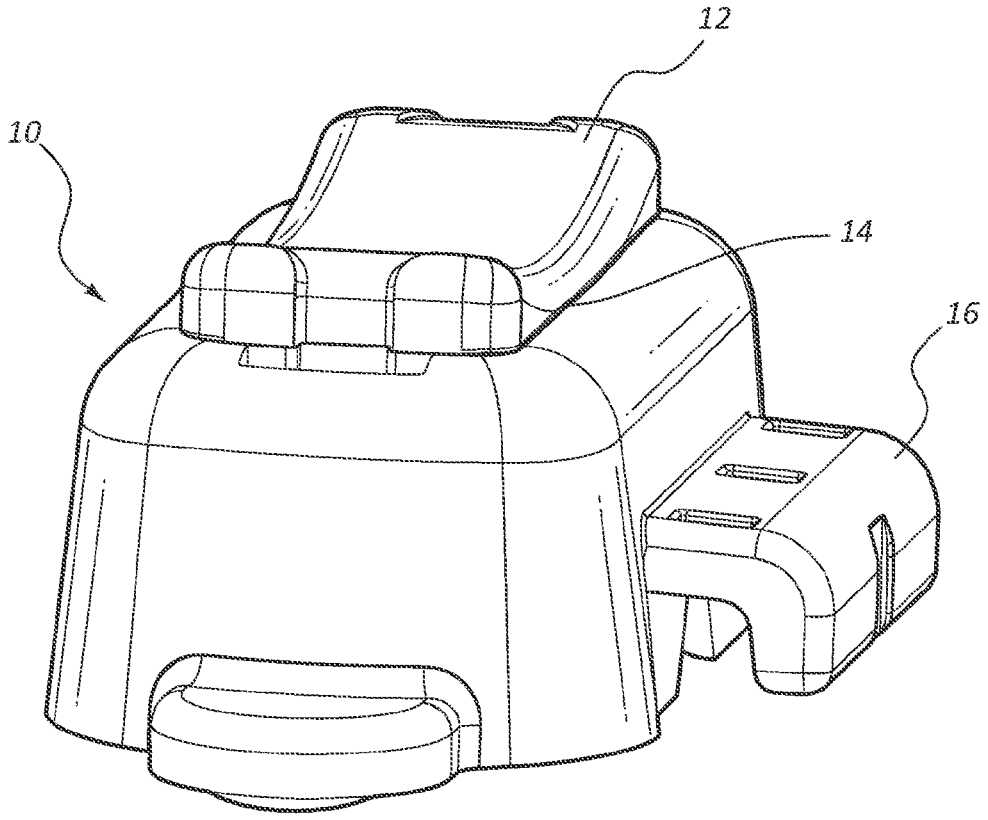


FIG. 1

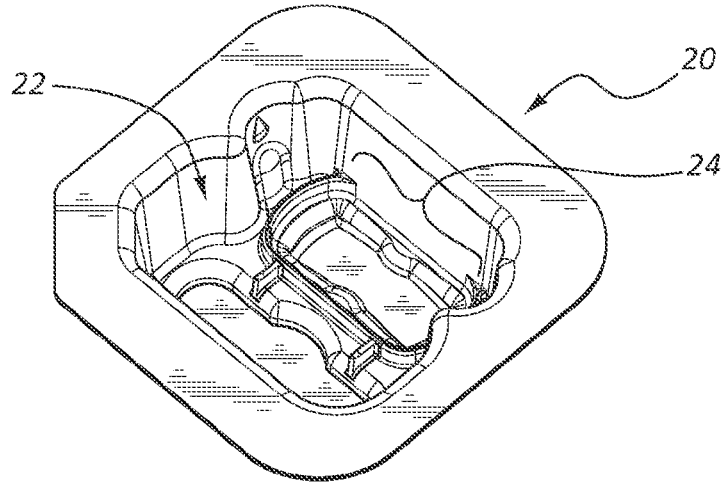


FIG. 2A

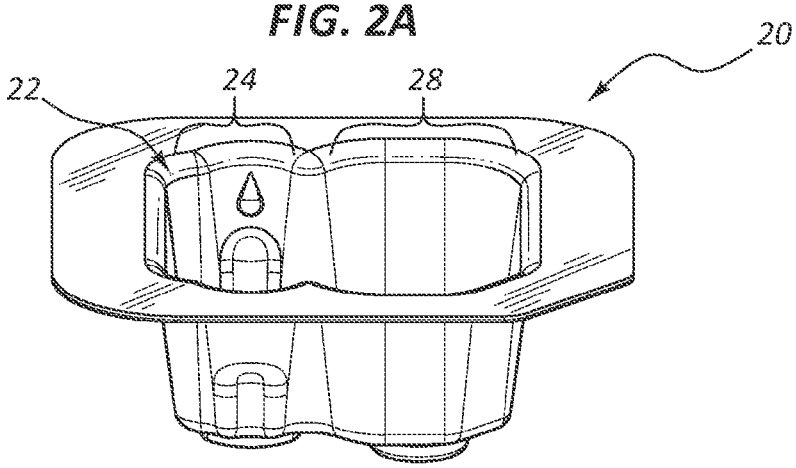


FIG. 2B

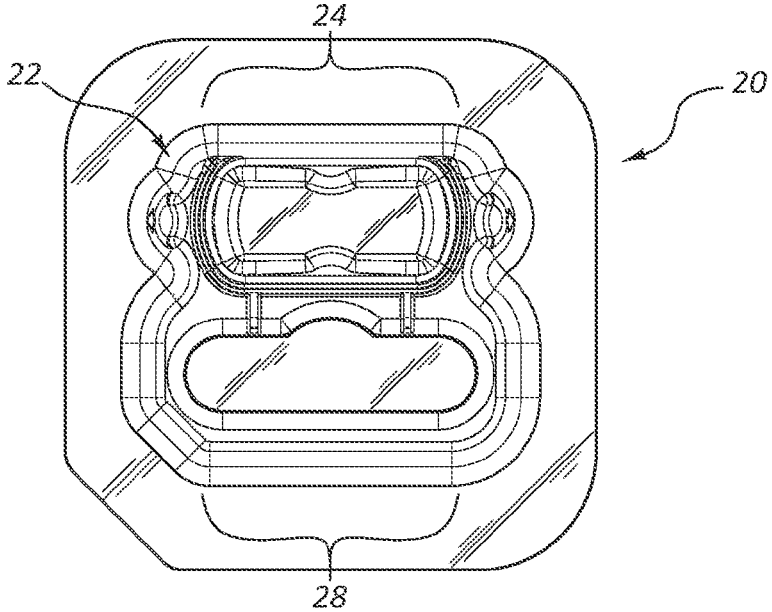


FIG. 2C

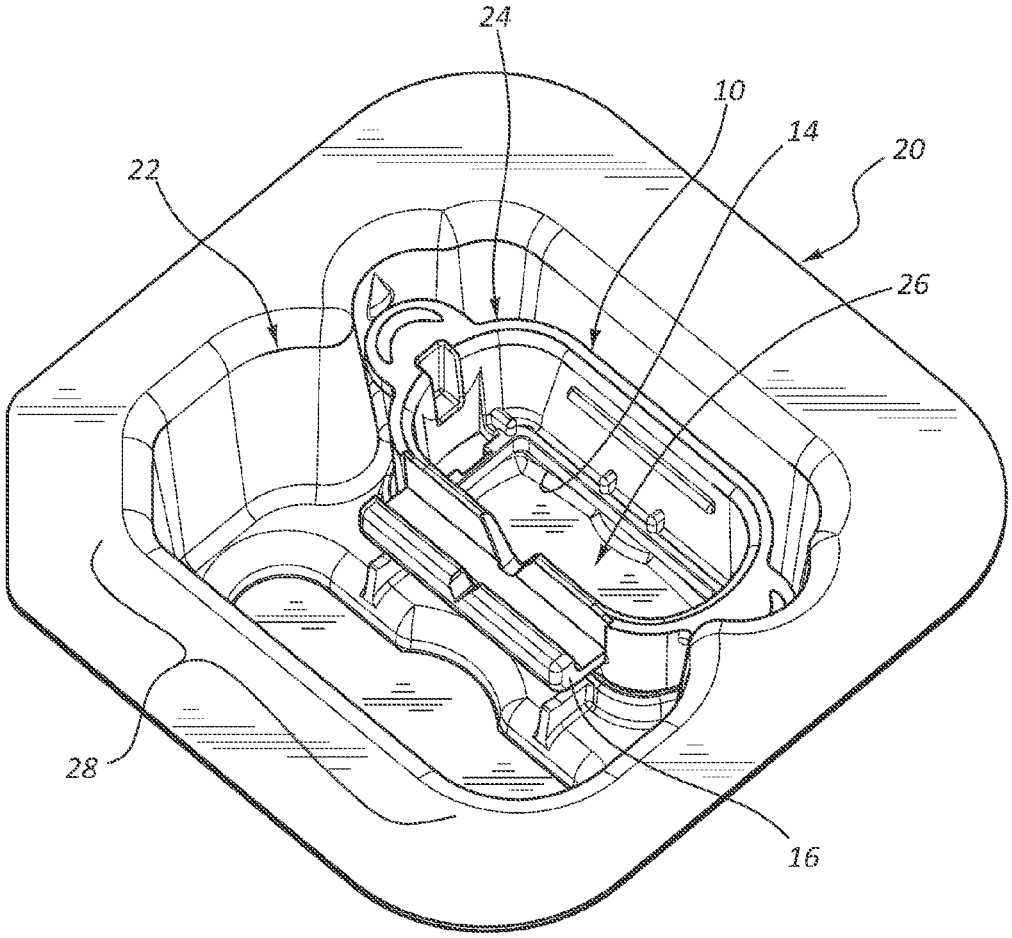


FIG. 3

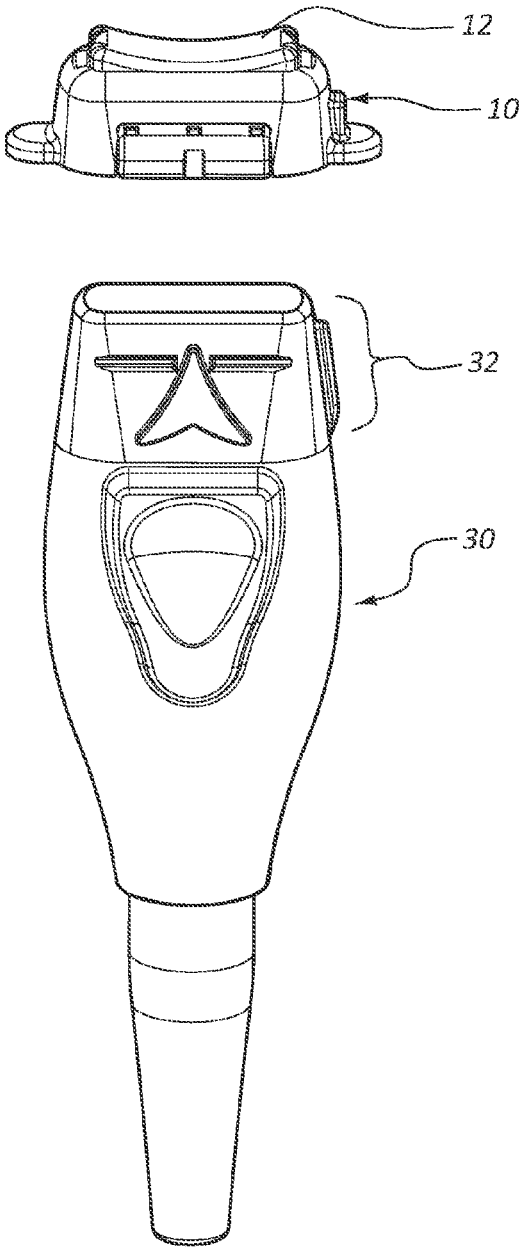


FIG. 4A

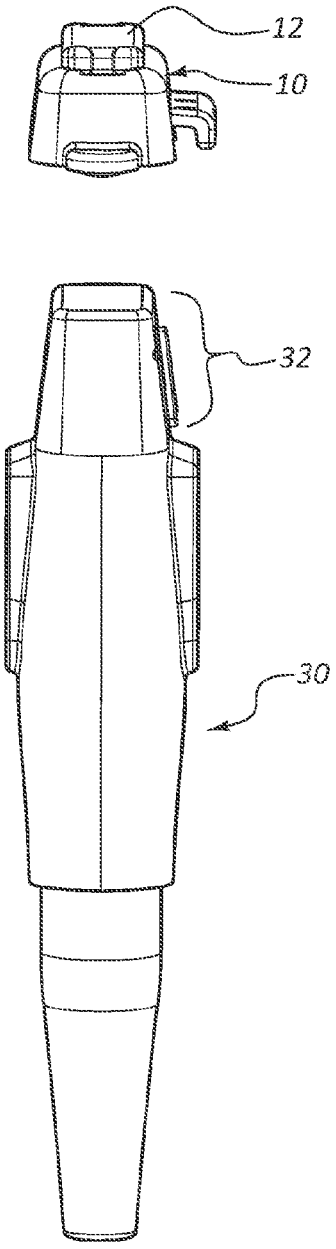


FIG. 4B

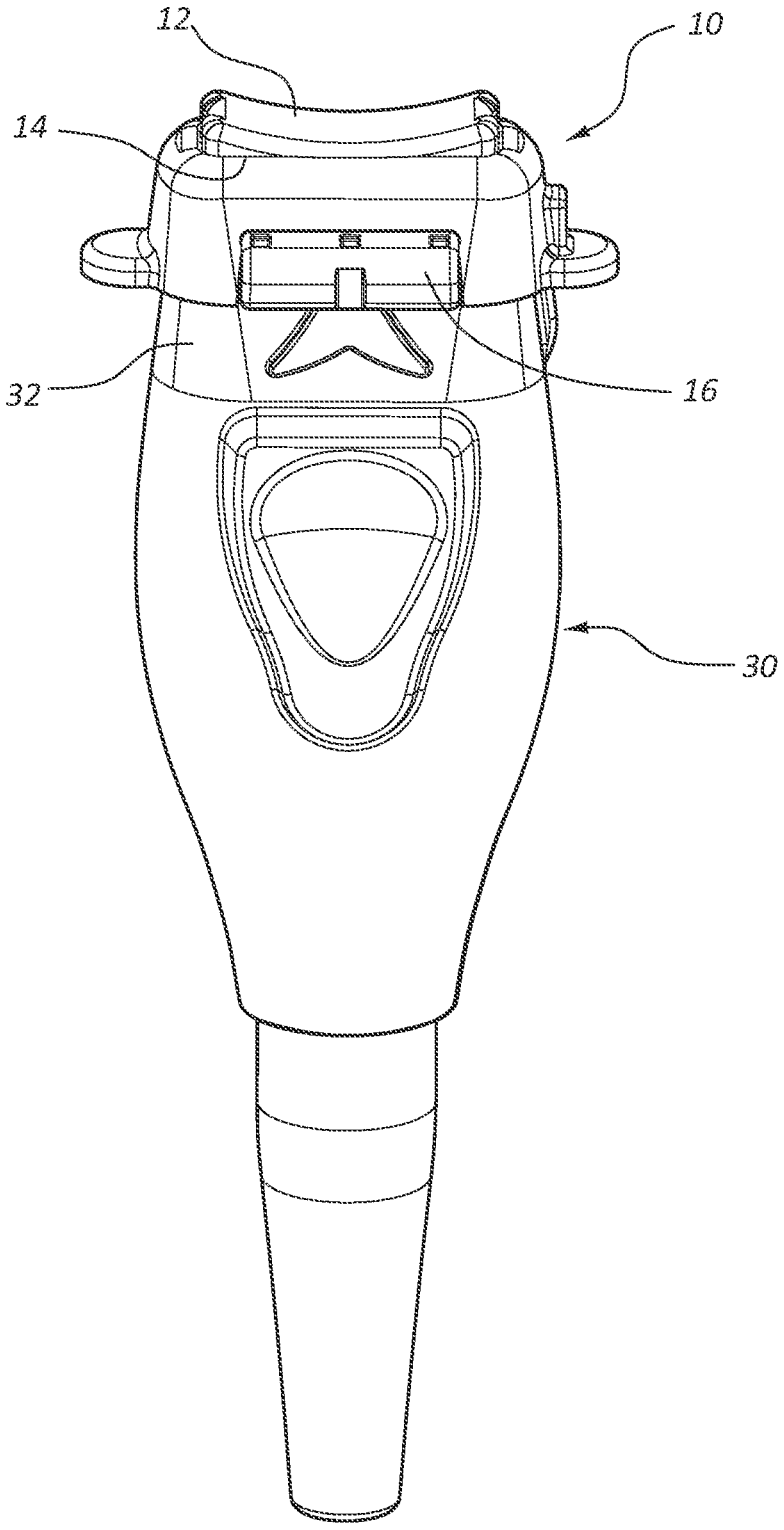
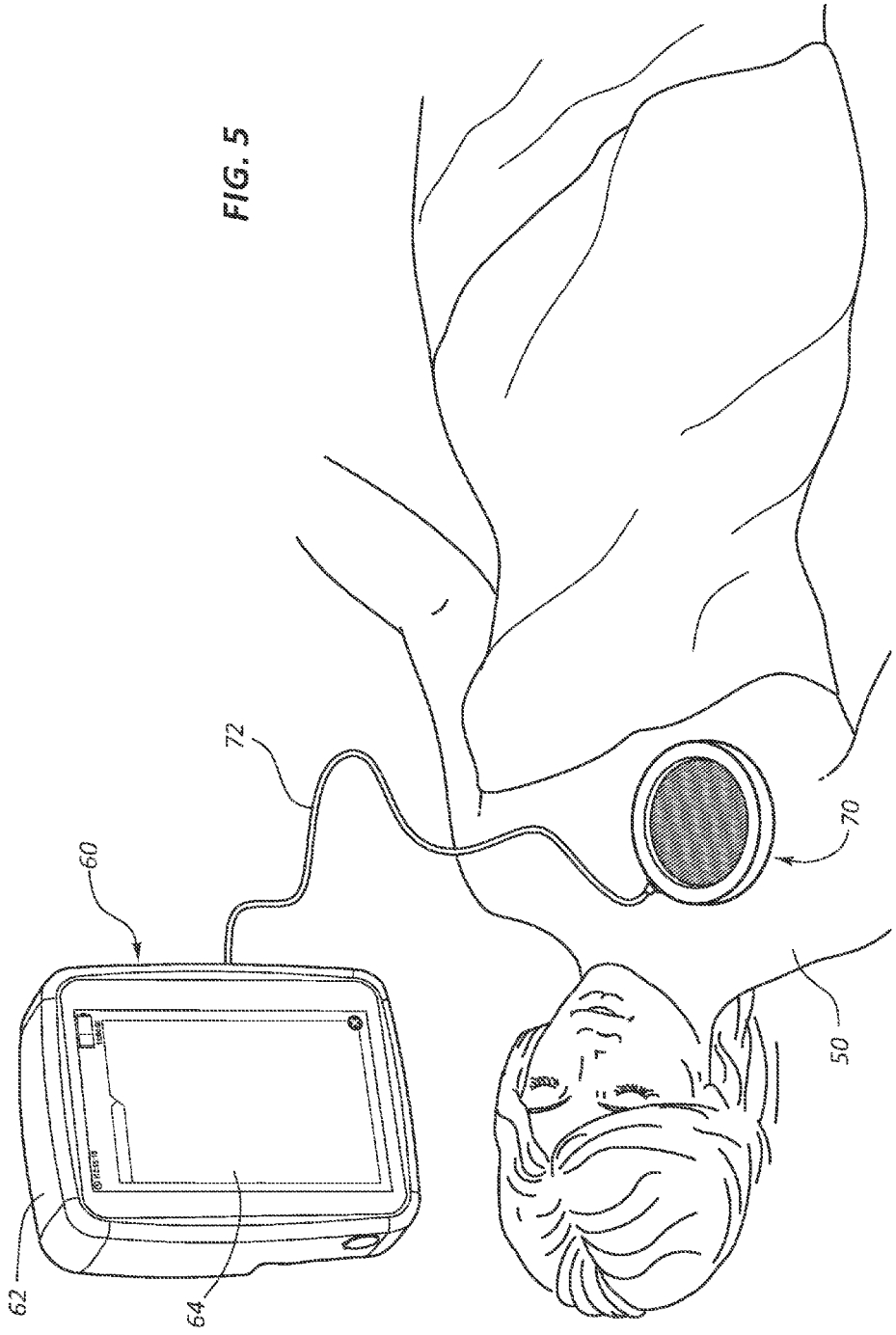


FIG. 4C

FIG. 5



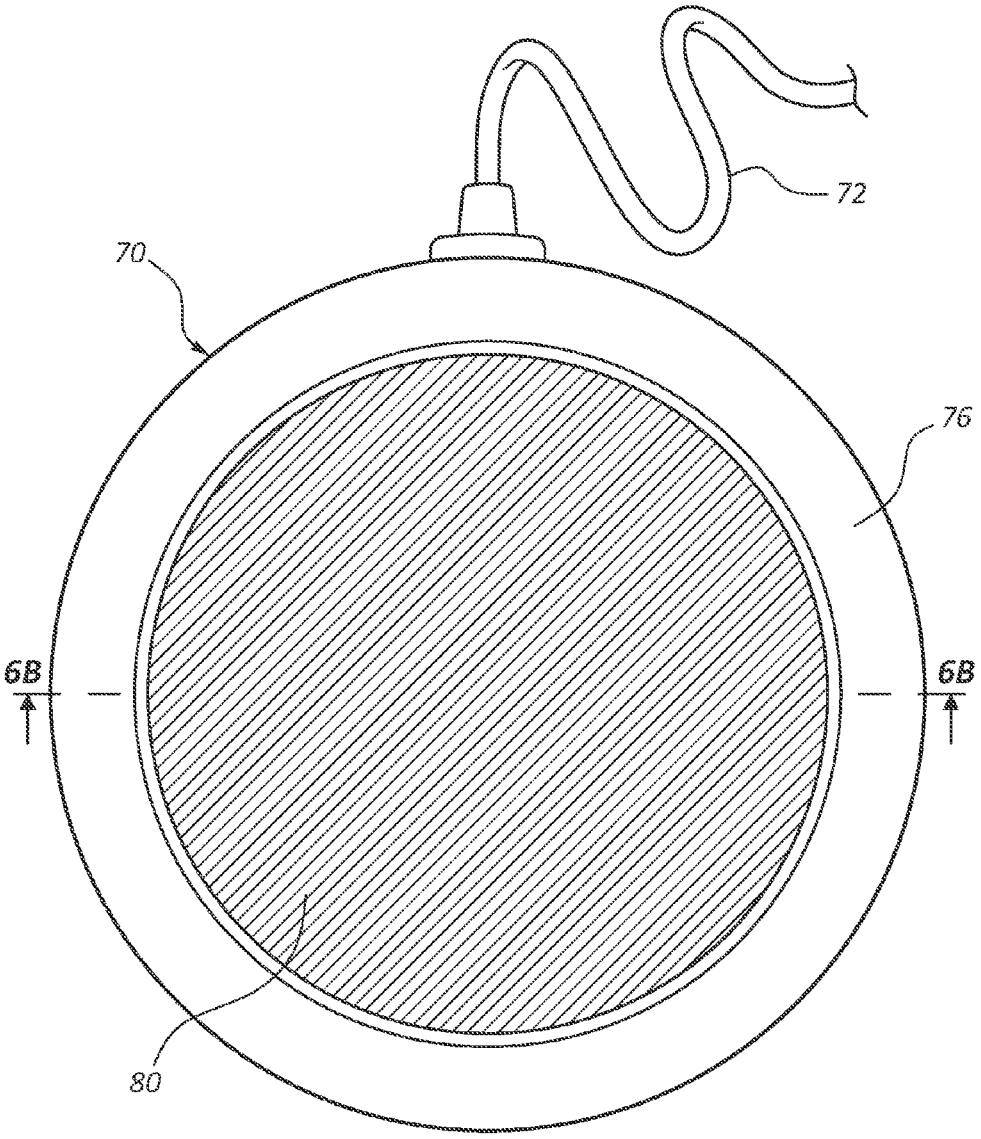


FIG. 6A

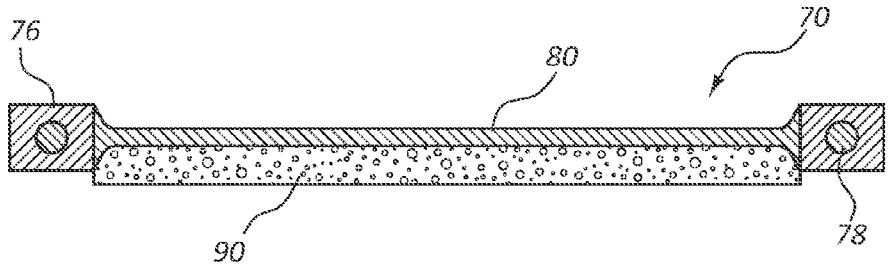


FIG. 6B

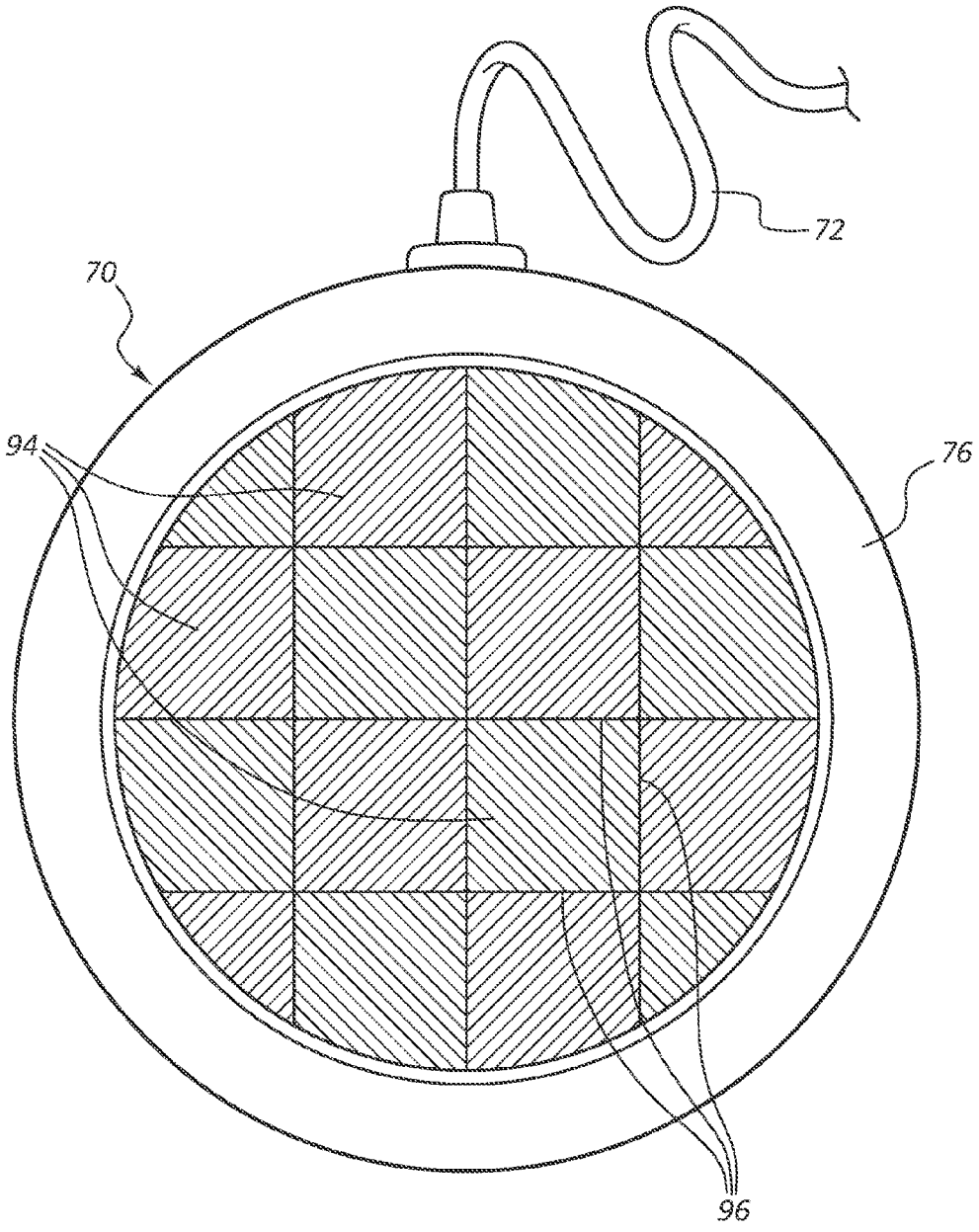


FIG. 7

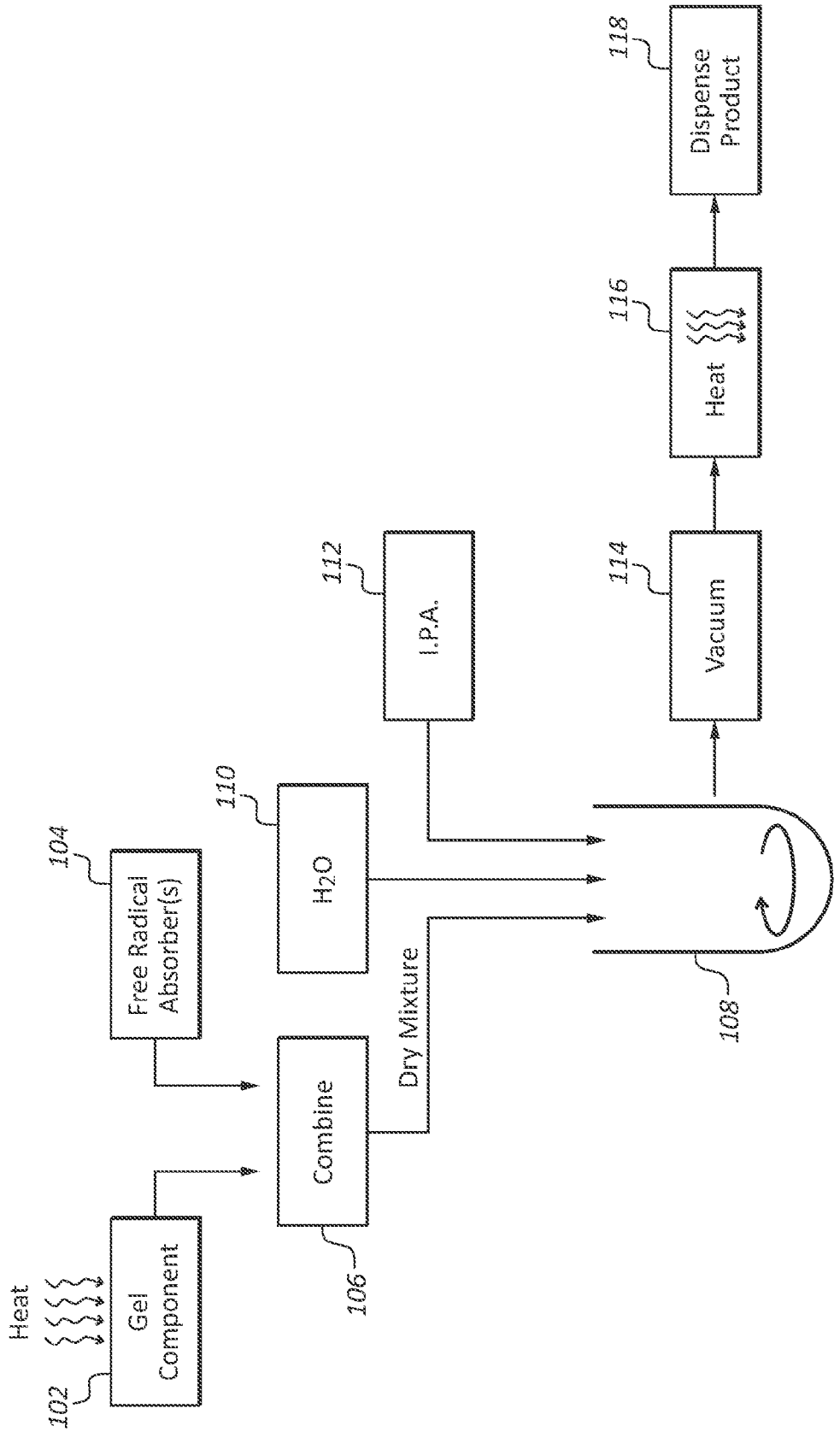

Heat
102
Gel Component
104
Free Radical Absorber(s)
106
Combine
110
H_2O
112
I.P.A.
Dry Mixture
108
114
Vacuum
116
Heat
118
Dispense Product

FIG. 8

RUGGEDIZED ULTRASOUND HYDROGEL INSERT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 61/563,382, filed Nov. 23, 2011, and titled "Ruggedized Ultrasound Hydrogel Insert," and U.S. Provisional Application No. 61/556,626, filed Nov. 7, 2011, and titled, "Systems and Methods for Ultrasound-Based Pneumothorax," each of which is incorporated herein by reference in its entirety.

BRIEF SUMMARY

Briefly summarized, embodiments of the present invention are directed to a ruggedized hydrogel product that is formulated to withstand the effects of high-energy sterilization procedures, such as gamma beam and electron beam sterilization, without significant structural degradation. This enables the hydrogel product to be suitable for use in medical applications where sterile components are required.

In one embodiment a ruggedized hydrogel product is disclosed and comprises a gel component, water for hydrating the gel component, and at least one free radical absorber component that is capable of absorbing free radicals produced when the hydrogel product is sterilized via high-energy sterilization procedures. The free radical absorber component in one embodiment includes potassium metabisulfite and ascorbic acid.

The ruggedized hydrogel product can be included with an ultrasound probe to provide an acoustically transparent interface between the probe and the skin of a patient. In one embodiment, the hydrogel is configured as an insert included with a cap that can be removably attached to the probe. In another embodiment, the hydrogel is configured as a slab that is attached to the bottom of a pancake probe. In addition, other configurations can also be employed.

These and other features of embodiments of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of embodiments of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

A more particular description of the present disclosure will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. Example embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

FIG. **1** is a perspective view of a cap for an ultrasound probe including a ruggedized hydrogel insert according to one embodiment;

FIGS. **2**A-**2**C are various views of a tray for housing the cap of FIG. **1** according to one embodiment;

FIG. **3** shows the cap of FIG. **1** disposed in the tray of FIGS. **2**A-**2**C according to one embodiment;

FIGS. **4**A and **4**B are exploded front and side perspective views of an ultrasound probe including the cap of FIG. **1** according to one embodiment;

FIG. **4**C is an assembled front perspective view of the ultrasound probe and cap of FIGS. **4**A and **4**B according to one embodiment;

FIG. **5** shows an ultrasound system including a probe for use with a patient according to one embodiment;

FIGS. **6**A and **6**B are various views of an ultrasound probe including a ruggedized hydrogel product according to one embodiment;

FIG. **7** is a top view of an ultrasound probe including a ruggedized hydrogel product according to one embodiment; and

FIG. **8** is a flow diagram showing preparation and dispensing of a ruggedized hydrogel product according to one embodiment.

DETAILED DESCRIPTION OF SELECTED EMBODIMENTS

Reference will now be made to figures wherein like structures will be provided with like reference designations. It is understood that the drawings are diagrammatic and schematic representations of exemplary embodiments of the present invention, and are neither limiting nor necessarily drawn to scale.

For clarity it is to be understood that the word "proximal" refers to a direction relatively closer to a clinician using the device to be described herein, while the word "distal" refers to a direction relatively further from the clinician. For example, the end of a catheter placed within the body of a patient is considered a distal end of the catheter, while the catheter end remaining outside the body is a proximal end of the catheter. Also, the words "including," "has," and "having," as used herein, including the claims, shall have the same meaning as the word "comprising."

Embodiments of the present invention are generally directed to a ruggedized hydrogel product that is formulated to withstand the effects of high-energy sterilization procedures, such as gamma beam and electron beam ("e-beam") sterilization, without significant structural degradation. This enables the hydrogel product to be suitable for use in medical applications where sterile components are required.

For example, the ruggedized hydrogel product can be included in one embodiment for use with an ultrasound probe. Particularly, the hydrogel product in one embodiment is positioned between a head portion of the probe and the patient's skin so as to act as an acoustically coupling interface during use of the probe in imaging subcutaneous tissue of the patient. This enables ultrasound signals emitted and received by the probe head to be efficiently transmitted between the head and the patient's body through the hydrogel, thus improving the quality of images produced by the ultrasound signals.

In addition, the hydrogel includes a substantial amount of water, which is exuded therefrom during use, thus providing a low friction interface that enables smooth sliding movement of the probe atop the skin. The relatively high water content of the hydrogel also mimics the composition of tissue in the patient's body, thus providing a relatively uniform medium for the transmission of ultrasound signals into and out of the body. Moreover, the hydrogel as disclosed herein is solid but compliant so as to conform to variations in the skin surface, thus enhancing the ability to maintain acoustic coupling between the probe head and the patient's body when the probe is slid over the patient's skin.

As mentioned above, the hydrogel product is both biocompatible and sterilizable so as to be usable in standard clinical environments. In particular, the hydrogel formulations disclosed herein can be subjected to standard sterilizing procedures, such as gamma beam and electron beam sterilization, without liquefying or otherwise physically degrading. This enables the hydrogel to successfully and safely undergo sterilization procedures together with other components to be sterilized, such as within a kit for instance, which increases manufacturing efficiency. In addition, the hydrogel can be configured to withstand other forms of sterilization/sterilizing materials, including ultraviolet light, hydrogen peroxide, ozone, and corona discharge treatment, in one embodiment. As used herein, "hydrogel" is understood to include a polymer network dispersed in water, often exhibited as a semi-solid gel.

Reference is made to FIG. **1**, which depicts a cap **10** for use with an ultrasound probe, such as the probe **30** shown in FIGS. **4**A-**4**C, according to one embodiment. The cap **10** is configured to operably attach to the probe **30** in a snap-fit or other suitable arrangement so as to cover at least a portion of a head portion **32** of the probe. Further details regarding the ultrasound probe **30** are given further below.

A hydrogel insert **12** including a hydrogel product configured in accordance with one embodiment is included with the cap **10**. As shown in FIG. **1**, the insert **12** is disposed in an opening **14** defined in the cap **10** so as to be secured in the configuration shown. The distal end of the insert **12** defines a concave shape to act, in one embodiment, as a standoff component for providing a physical separation between the ultrasound probe **30** (FIGS. **4**A-**4**C) and the patient's skin, thus preventing compression of superficial veins beneath the skin and therefore enabling suitable imaging thereof. In the present embodiment, a fixture **16** is included on the cap **10** for receipt of a needle guide to help guide a needle into the patient after a suitable vessel has been found via ultrasound imaging. Further details regarding the cap and needle guide can be found in U.S. Publication No. 2011/0313293, filed Aug. 9, 2011, and U.S. Publication No. 2012/0165679, filed Dec. 22, 2011, and titled "Selectable Angle Needle Guide", each of which is incorporated herein by reference in its entirety. It should be noted that the discussion herein concerning the hydrogel component and its use with an ultrasound probe is merely an example of one implementation thereof and should not be considered limiting of the range of possible uses for the hydrogel product.

FIGS. **2**A-**2**C show a tray **20** that serves as a mold in the present embodiment for forming the hydrogel insert **12** of FIG. **1**, as will be described. The tray **20** includes a suitable material such as a thermoplastic and defines a cavity **22** for receiving various components therein. Specifically, a cap cavity portion **24** is defined in the cavity **22** and is shaped to removably receive therein the cap **10** of FIG. **1**. A convexly-shaped hydrogel insert cavity portion **26** is defined within the cap cavity portion **24** and is shaped to provide a mold surface and volume for defining the hydrogel insert **12** when the insert is manufactured, as will be described further below. Also included is a cavity area **28** adjacent the cap cavity portion **24** to provide a space where a needle guide can be disposed if attached to the cap.

FIG. **3** shows the cavity **22** of the tray **20** with the cap **10** disposed in the cap cavity portion **22** thereof. With the cap **10** so positioned a volume is defined, as mentioned, proximate the distal end of the cap **10** and the hydrogel insert cavity portion **26** in which the hydrogel product can be disposed and cured, as discussed further below, in order to form the hydrogel insert **12** in an attached configuration with the cap, as seen in FIG. **1**.

FIGS. **4**A-**4**C show the manner of attachment of the cap **10** to the head portion **32** of the ultrasound probe **30**. Surface features on the cap **10** and the head **32** are included to enable the cap to be removably attached to the head in a friction fit arrangement, though other attachment schemes may also be used. This places the hydrogel component of the insert **12** at the distal end of the probe **30** to provide an ultrasonically transparent interface between transducer elements disposed in the probe head **32** and the patient's skin. Again, the probe, the cap, and the manner in which the hydrogel component is configured and used can vary from what is shown and described herein.

As mentioned, the hydrogel product of the insert **12** of the cap **10** is used in medical applications to assist with ultrasonic imaging procedures, such as imaging a subcutaneous vessel in preparation for insertion of a catheter, needle, or other medical device therein. As such, the cap **10** and accompanying hydrogel insert must often be sterilized prior to use so as to prevent transmission of microbes, diseases, viruses, bacteria, and so forth. In the present embodiment the hydrogel product is formulated so as to withstand high-energy sterilization procedures that are typically used to sterilize medical devices and equipment.

Specifically, in one embodiment the hydrogel product from which the insert **12** is made includes a ruggedized formulation to provide the desirable qualities discussed above, including the ability to sterilize the hydrogel insert via gamma beam or electron beam sterilization procedures without causing physical degradation of the hydrogel. In one embodiment a hydrogel product is disclosed that includes various components, namely: a gel component to provide the gel structure itself, and water to hydrate the initially dry gel component. In accordance with the present embodiment, one or more free radical absorber components are also included in the composition to absorb free radicals that are produced in the hydrogel as a result of the high-energy sterilization process. Left unchecked, the free radicals cause undesired degradation and liquefying of the hydrogel, rendering it useless for the intended ultrasound-related uses discussed above. By including these absorbers in the hydrogel component, the free radicals are neutralized and are thus unable to cause hydrogel degradation.

According to one embodiment, non-limiting examples of free radical absorbers that can be utilized in the hydrogel of the insert **118** or other implementation include: glutathione, potassium metabisulfite, potassium disulfite, sodium formate, potassium formate, L-ascorbic acid, sodium citrate monobasic, L-glutamic acid monosodium salt, L-glutamic acid, catechin, organic compound-containing thiol, potassium iodide, vitamin E, cysteine, and other suitable absorbers including antioxidants employed in the food and cosmetics industry. Other salt forms of the above compounds can also be employed as suitable free radical absorbers. For instance potassium formate, a salt compound related to sodium formate, can be also be employed as a free radical absorber. In addition to the gel component and free radical absorber components, and water, other additive components can be included, including mixing aids, preservatives, etc.

In light of the above, in one example embodiment a hydrogel product includes the following composition:

TABLE 1

Category	Component	Quantity (percentage by weight, per each hydrogel unit)
Gel Component	Carrageenan Gum & Konjac Gum	About 2.09%
Free Radical Absorber	Potassium Metabisulfite	About 1.86%
Free Radical Absorber	Ascorbic Acid	About 0.025%
Additive	Isopropyl Alcohol	About 0.95%
Hydrating Medium	Deionized Water	About 95.07%

As seen in Table 1, the hydrogel component according to the present embodiment includes a gel component, two free radical absorber components, an additive, and water as a hydrating medium. The gel component in the present embodiment includes a hydrogel powder product, Stabilizer VPB-1, sold under the trademark COYOTE and manufactured by Gum Technology of Tucson, Ariz. Comparable products are attainable from other sources. The Stabilizer VPB-1 powder gel component includes both carrageenan gum and konjac gum and provides the base for the hydrogel product. In one embodiment, the Stabilizer VPB-1 powder gel component includes a particle size of 90% minimum passage through a U.S. Standard 40 mesh sieve and can include potassium chloride and/or calcium chloride to provide standardization thereof.

The free radical absorbers of Table 1 include potassium metabisulfite (also known as potassium disulfite) and ascorbic acid, otherwise known as vitamin C. Each of these provides stability to the hydrogel component in absorbing free radicals created in the hydrogel during subsequent high-energy sterilization procedures. In the present embodiment, the potassium metabisulfite is initially in powder form and possesses a purity of greater than or equal to about 95%. The ascorbic acid is also initially in powder form and possesses a purity equal to or exceeding about 99%. In one embodiment, the above components can generally meet food or nutriceutical grade for use in the present hydrogel product formulation. It is appreciated that the term "powder" herein can include various physical forms including particulate, granular, crystalline, crushed, etc.

The additive isopropyl alcohol ("IPA") in the present embodiment is of USP grade at a purity of equal to or exceeding 99%. The IPA aides in the dissolving and/or mixing of the other ingredients during hydrogel manufacture and also assists in neutralizing the scent of the hydrogel created by the free radical absorbers components. The water serves as the hydrating medium for the hydrogel product and subsequently provides the acoustic transparency necessary for the hydrogel product. In the present embodiment, deionized water is employed to provide an acceptable purity level. However, in other embodiments other forms of water with a low bioburden or contaminant level can be employed, including sterile water, distilled water, filtered water, etc. Note also that the relative concentrations or inclusion of the various components can be varied from what is shown herein.

FIG. **8** provides a flow diagram **100** describing various stages of the preparation of the hydrogel product described herein. Though directed toward preparation of the hydrogel product having the formulation depicted in Table 1 above, the flow diagram **100** can also be applied to other possible hydrogel formulations, including those additionally described herein. At stage **102** the dry powder gel component, i.e., the Stabilizer VPB-1 powder in the present embodiment, can be subjected to a pre-treatment heating process in order to reduce or eliminate any bio-burden, or presence of undesired biological entities (microbes, insects, etc.) In the present embodiment, the gel component is subjected to oven heating at about 120 degrees Celsius for about 4 to 5 hours.

At stage **106**, a measured amount the pre-treated gel component is combined with measured amounts of the powder forms of the free radical absorber components **104**, i.e., the potassium metabisulfite and ascorbic acid in the present embodiment. In one embodiment, combining of these components is achieved via dry-mixing. In another embodiment, the powder components are merely combined without active mixing.

At stage **108**, the combined powder from stage **106** is mixed into a vessel with measured amounts of deionized water, represented at block **110**, and IPA, represented at block **112**. In the present embodiment, the liquid IPA is added to the deionized water already present in the vessel before the dry-mixed powder is introduced into the vessel. In another embodiment, the IPA and water can be added at the same time. A mechanical mixer can be used and the dry-mixed powder added slowly to the deionized water/IPA mixture to ensure dispersion and dissolving of the powder. The hydrated mixture ("hydrogel solution") is mixed for about two minutes after all the components have been added, in the present embodiment.

At stage **114**, the hydrogel solution is subjected to a vacuum in order to reduce or eliminate any air bubbles in the mixture. In the present embodiment, the vessel used at stage **108** is a pressure vessel suitable for providing a vacuum so the hydrogel solution need not be transferred to another container. The vacuum is applied to the hydrogel solution a minimum of 10 minutes in the present embodiment so that all or most air bubbles trapped in the solution are released. The hydrogel solution can then be inspected to ensure it is smooth and substantially bubble-free. If not, the vacuum process can be repeated.

At stage **116** the hydrogel solution is heated to a temperature of about 85-90 degrees Celsius to keep it flowable in preparation for dispensing it at stage **118** and completing preparation of the hydrogel product. Of course, the heating temperature and other details of the procedure described herein can be varied in accordance with alterations in the hydrogel formula, intended use, etc., as appreciated by one skilled in the art. In the present embodiment, the hydrogel solution is loaded into a suitable pumping/dispensing device. Note that the dispensing device can also provide the needed heating of the solution shown at stage **116**.

With respect to dispensing the hydrogel solution of stage **118**, in one embodiment the solution is dispensed into a portion of the tray **20** shown and described in connection with FIGS. **2A-3**. In particular, the hydrogel solution can be dispensed into the volume defined by the hydrogel insert cavity portion **26** when the cap **10** is disposed within the tray **20**. As mentioned, the portion of the tray **20** that defines the hydrogel insert cavity portion **26** is shaped so as to impart the desired shape of the hydrogel insert **12** (see FIG. **1**) when the hydrogel solution solidifies after dispensing.

In the present embodiment, the dispensing stage **118** includes placing the cap **10** (FIG. **1**) in the cap cavity portion **24** of the cavity **22** of the tray **20** as shown in FIG. **3**. In one embodiment a needle guide can be attached to the cap **10** prior to placing it in the tray **20**; if so, the needle guide is disposed in the cavity area **28** of the tray cavity **22** when the cap is placed in the tray.

Once the cap is disposed in the tray, the cap **10** can be treated with a corona discharge treatment process to improve

cap surface characteristics for receipt of the hydrogel solution that will solidify to form the hydrogel insert **12**, FIG. **1**.

After the corona discharge treatment the hydrogel solution, which is heated as previously described to maintain flowability, is dispensed from a suitable dispenser into the hydrogel insert cavity portion **26** of the tray cavity **22** in sufficient quantity to fill the cavity portion and backfill into the cap **10** via the opening **14** thereof a limited amount. Inspection after filling may indicate if air bubbles are present, the fill was insufficient or non-uniform or messy, etc. such that corrective measures may be taken.

After dispensing of the hydrogel solution into the cap **10** within the tray **20**, the tray is left flat for at least 30 seconds in one embodiment to ensure that the hydrogel solution properly cures and solidifies into the hydrogel insert **12** (FIG. **1**). As a portion of the hydrogel solution solidifies within the volume defined by the cap **10**, attachment between the hydrogel and the cap is achieved. Note that the above-described procedures can be performed for each cap individually or in a batch process where multiple caps are filled with hydrogel solution. Note also that this is but one possible use for the ruggedized hydrogel; other hydrogel applications can also benefit from the principles described herein.

After curing of the hydrogel solution, the cap **10** and newly-formed hydrogel insert **12** can be sterilized by high-energy sterilization procedures without being removed from the tray **20**. As described, because of its formulation the hydrogel product can withstand such high-energy sterilization without undesirably degrading and liquefying. In one example, the hydrogel product was exposed to about 30 kGy of ionizing radiation (gamma beam) sterilization without significant resultant hydrogel degradation.

Once sterilization is complete, the tray **20**, including the cap **10** and attached hydrogel insert **12** disposed therein, can be packaged, stored, used, etc. For instance, the cap **10** in one embodiment may be attached to and used with an ultrasound probe, such as the probe **30** shown in FIG. **4**C.

Below are various examples of preparations of a hydrogel product in accordance with embodiments of the present disclosure.

EXAMPLE 1

A hydrogel product was prepared by first pre-treating about 100 grams of Gum Tech Stabilizer VPB-1 powder in an oven for about four hours at about 120 degrees Celsius. About 86.0 to about 89.9 grams of the pre-treated Stabilizer VPB-1 powder was then combined with about 75.7 to about 80.0 grams of potassium metabisulfite powder and about 1.01 to about 1.06 grams of ascorbic acid powder to form a hydrogel powder. The hydrogel powder was then mixed into an aqueous solution of about 4,000 ml of deionized water and about 40 ml of isopropyl alcohol for approximately two minutes after all of the hydrogel powder had been added to the aqueous solution. A vacuum cycle of about 10 minutes was then applied to the resultant hydrogel solution to remove any air bubbles. The hydrogel solution was then heated to a temperature of from about 85 to about 90 degrees Celsius and dispensed to a tray mold. The molded hydrogel solution was allowed to cure for about 30 seconds to form a completed hydrogel product. Note that the purities and other characteristics of the components of the hydrogel solution of the present example are similar to those described in the above discussion relating to FIG. **8**.

EXAMPLE 2

A hydrogel product was prepared by first combining dry powders of the following components in the specified concentrations (percentages are w/w- by weight) to form a hydrogel powder: gel component: kappa-carrageenan gum- about 0.7%; iota-carrageenan gum- about 0.3%; konjac gum- about 0.5%; potassium chloride- about 0.010% (about 8 milliMolar ("mM")); free radical absorber components: L-ascorbic acid- about 2.5% (about 140 mM); potassium metabisulfite- about 1.33% (about 50 mM); preservatives: propyl 4-hydroxybenzoate- about 0.18% (about 1.0 mM); methyl 4-hydroxybenzoate- about 0.05% (about 0.4 mM). The hydrogel powder was then mixed into an aqueous solution to form a hydrogel solution. The aqueous solution included isopropyl alcohol comprising about 4% (about 500 mM) of the total hydrogel solution and deionized water comprising about 90.66% of the total hydrogel solution. The hydrogel solution was mixed for at least two minutes after all of the hydrogel powder had been added to the aqueous solution. The hydrogel solution was then heated and dispensed to a mold. The molded hydrogel solution was allowed to cure to form a completed hydrogel product.

EXAMPLE 3

A hydrogel product was prepared by first combining dry powders of the following components in the specified concentrations (percentages are w/w- by weight) to form a hydrogel powder: gel component: kappa-carrageenan gum- about 0.7%; iota-carrageenan gum- about 0.3%; konjac gum- about 0.5%; potassium chloride- about 0.010% (about 8 milliMolar ("mM")); free radical absorber components: L-ascorbic acid- about 2.5% (about 140 mM); glutathione- about 1.2% (about 40 mM); preservatives: propyl 4-hydroxybenzoate- about 0.18% (about 1.0 mM); methyl 4-hydroxybenzoate- about 0.05% (about 0.4 mM). The hydrogel powder was then mixed into an aqueous solution to form a hydrogel solution. The aqueous solution included isopropyl alcohol comprising about 4% (about 500 mM) of the total hydrogel solution and deionized water comprising about 90.56% of the total hydrogel solution. The hydrogel solution was mixed for at least two minutes after all of the hydrogel powder had been added to the aqueous solution. The hydrogel solution was then heated and dispensed to a mold. The molded hydrogel solution was allowed to cure to form a completed hydrogel product.

EXAMPLE 4

A hydrogel product was prepared by first combining dry powders of the following components in the specified concentrations (percentages are w/w- by weight) to form a hydrogel powder: gel component: kappa-carrageenan gum- about 0.7%; iota- carrageenan gum- about 0.3%; konjac gum- about 0.5%; potassium chloride- about 0.010% (about 8 milliMolar ("mM")); free radical absorber components: L-ascorbic acid- about 2.5% (about 140 mM); sodium formate- about 2.0% (about 300 mM); preservatives: propyl 4-hydroxybenzoate- about 0.18% (about 1.0 mM); methyl 4- hydroxybenzoate- about 0.05% (about 0.4 mM). The hydrogel powder was then mixed into an aqueous solution to form a hydrogel solution. The aqueous solution included isopropyl alcohol comprising about 4% (about 500 mM) of the total hydrogel solution and deionized water comprising about 89.76% of the total hydrogel solution. The hydrogel solution was mixed for at least two minutes after all of the hydrogel powder had been added to the aqueous solution. The hydrogel solution was then heated and dispensed to a mold. The molded hydrogel solution was allowed to cure to form a completed hydrogel product.

It is appreciated that in other embodiments the formulations identified in Examples 2-4, can omit the preservatives

propyl 4-hydroxybenzoate and methyl 4-hydroxybenzoate from the hydrogel product formulation. In another embodiment, the free radical absorber ascorbic acid can be omitted from the hydrogel product formulation. In yet another embodiment, a suitable antibacterial/antimicrobial component could be added to the hydrogel formulation. IPA can be varied in concentration, such as from about one to about five percent by weight in one embodiment, or omitted from the composition in one embodiment. Indeed, if IPA is omitted from the hydrogel formulation, a small amount could still be added to an external portion of the hydrogel product post-manufacture so as to assist in masking any unpleasant smell of the hydrogel. Other aromatic or fragrant substances can optionally be used to mask the hydrogel odor. It is also appreciated that other gel components in addition to those listed herein can be employed, including polysaccharide-based gel components, for instance.

In yet another embodiment, it is appreciated that the hydrogel product can include a component to render the hydrogel bacteriostatic. In such a case, it may be chosen to not sterilize the hydrogel product, but rather rely on its bacteriostatic qualities. In one embodiment, a suitable substance, such as chlorhexadine, can be added to the hydrogel component to render it bacteriostatic. In this instance, the IPA could be included or omitted from the hydrogel formulation.

Reference is now made to FIG. **5** in describing one possible implementation of a ruggedized hydrogel product according to one embodiment. A patient **50** is shown undergoing an ultrasound imaging procedure with the use of an ultrasound imaging system **60**, which includes a console **62** housing a display **64**. An ultrasound probe **70**, configured in accordance with one embodiment, is operably connected to the console **62** via a cable **72** or other suitable connective scheme and is positioned atop a portion of the patient's chest in order to provide ultrasonic images of a vessel or other subcutaneous features.

FIGS. **6**A and **6**B depict further details regarding the ultrasound probe **70** depicted in FIG. **5**. The probe **70** has a general pancake shape and includes a flexible, annular perimeter portion **76** that is configured to be deformable. A reinforcement ring **78** is embedded within the perimeter portion **76** so as to limit the range of deformation for the probe **70**. In one embodiment, the reinforcement ring **78** can be configured to maintain the deformation of the probe **70** when deformed by a clinician in order to conform to a particular body contour of the patient.

A transducer **80** is included in the central portion of the probe **70** such that it is bounded by the perimeter portion **76**. In the present embodiment, the transducer **80** includes polyvinylidene fluoride ("pvdf"), which is a non-reactive and pure thermoplastic fluoropolymer that is also a piezoelectric material. As such, the pvdf material can serve as a transducer element for the transducer **80** in producing and detecting ultrasonic signals. Like the perimeter portion **76**, the pvdf transducer is also flexible. The flexible nature of the perimeter portion **76** and the pvdf transducer **80** thus enables the probe to conform to body contours when it is placed upon the body of the patient.

FIG. **6**B shows that the probe **70** further includes a hydrogel slab **90** that is positioned on a bottom surface of the transducer **80** so as to provide an acoustically transparent interface between the transducer and the body of the patient. In the present embodiment, the hydrogel slab **90** is manufactured as described herein so as to exhibit ruggedized characteristics and be able to withstand high-energy sterilization procedures. Thus, the hydrogel slab **90** of FIG. **6**B shows one example of an optional use of the ruggedized hydrogel product described herein in addition to implementations already described.

FIG. **7** shows the pancake ultrasound probe **70** according to another embodiment, wherein the transducer includes a plurality of discrete transducer elements **94** that are physically and electrically isolated separated from one another by insulting dividers **96** of plastic or other suitable material. These and other transducer designs are therefore contemplated. In one embodiment, the probe **70** is employed in an A-mode ultrasound imaging setting to detect the presence of pneumothorax in a patient following the placement of a catheter of other device into the vasculature of the patient in the case where the device has punctured the lung. Differences noted in the A-mode ultrasound profile of the subcutaneous area of interest before and after catheter placement can indicate the presence of pneumothorax. Of course, the probe can be employed in other applications.

Embodiments of the invention may be embodied in other specific forms without departing from the spirit of the present disclosure. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the embodiments is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A cap for an ultrasound probe, comprising:
- a body defining a cavity into which a portion of an ultrasound probe is received; and
- a ruggedized low-friction hydrogel insert operably attached to the body, the low-friction hydrogel insert comprising:
  - a gel component including carrageenan gum and konjac gum;
  - isopropyl alcohol;
  - deionized water; and
  - a free radical absorber component for absorbing free radicals produced when the low-friction hydrogel insert is subjected to a high-energy sterilization procedure, the free radical absorber component including at least one of potassium metabisulfite and ascorbic acid.

2. The cap as defined in claim **1**, wherein the free radical absorber component includes both potassium metabisulfite and ascorbic acid.

3. An ultrasound probe, comprising
- a body including a transducer; and
- a ruggedized hydrogel product operably attached to the body to provide for a low friction interface, the hydrogel product comprising:
  - a gel component;
  - isopropyl alcohol;
  - deionized water; and
  - a free radical absorber component for absorbing free radicals produced if the hydrogel product is subjected to at least one of a gamma beam sterilization procedure and an electronic beam sterilization procedure.

4. The probe as defined in claim **3**, wherein the free radical absorber component includes at least one of potassium metabisulfite and ascorbic acid and wherein the gel component includes a gum component.

5. The probe as defined in claim **3**, wherein the probe is a flexible pancake probe and wherein the hydrogel product is slab-shaped and positioned on a bottom surface of the pancake probe.

6. The probe as defined in claim 5, wherein the pancake probe includes a flexible outer perimeter that bounds a flexible transducer, the transducer including polyvinylidene fluoride.

7. The probe as defined in claim 6, wherein the transducer is segmented into a plurality of discrete transducer elements.

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